

Appl. No. : **10/825,085**
Filed : **April 15, 2004**

AMENDMENTS TO THE DRAWINGS

Please replace Figures 25, 30A, 30B, 31A, 31B, 34A, 34B, 35A, and 35B with the revised Figures 25, 30A, 30B, 31A, 31B, 34A, 34B, 35A, and 35B provided on the replacement sheets submitted herewith.

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REMARKS

The foregoing amendments and the following remarks are responsive to the May 3, 2006 Office Action. Claims 1, 10, 11, 13, 14, 17, 27, 30-33, and 36 are amended, Claims 9, 25, 26, 28, and 29 are cancelled without prejudice, and Claims 2-8, 12, 15, 16, 18-24, 34-35, and 37-49 remain as originally filed. Thus, Claims 1-8, 10-24, 27, and 30-49 are presented for further consideration. Please enter the amendments and reconsider the claims in view of the following remarks.

Allowed Claims

Applicants gratefully acknowledge the Examiner's statement that Claims 14-16, 27, and 30 would be allowable if re-written to overcome the 35 U.S.C. §112, 2nd paragraph rejections and to include all the limitations of the base claim and any intervening claims. However, Applicants note that there were no 35 U.S.C. §112 rejections of these claims made in this office action. Applicants also gratefully acknowledge the Examiner's statement that Claims 39-48 are allowed.

Applicants have amended Claims 14, 27, and 30 to include all the limitations of the base claim and any intervening claims. Each of Claims 15 and 16 depends from Claim 14, so each of Claims 15 and 16 also includes all the limitations of the base claim and any intervening claims. Accordingly, Applicants submit that Claims 14-16, 27, and 30 are in condition for allowance.

Response to Objections to Drawings

The Examiner objects to Figures 25, 30A, 30B, 31A, 31B, 34A, 34B, 35A and 35B because the lines are indistinguishable and not labeled. Applicants have amended Figures 25, 30A, 30B, 31A, 31B, 34A, 34B, 35A and 35B to distinguish and label the lines in each graph as suggested by the Examiner. Accordingly, Applicants respectfully request the Examiner to withdraw the objection to Figures 25, 30A, 30B, 31A, 31B, 34A, 34B, 35A and 35B.

Response to Objections to the Specification

The Examiner objects to paragraph [0145] because the paragraph makes reference to chamber walls 202 which does not appear on any figure. The examiner notes that the chamber walls are designated 202a, 202b, 202c and 202d in the figures. Applicants have amended paragraph [0145] to refer to chamber walls 202a-d as suggested by the Examiner. Accordingly, Applicants respectfully request the Examiner to withdraw the objection to paragraph [0145].

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Response to Objections to Claims 33 and 36

Claim 33

The Examiner objects to Claim 33 for being indefinite because of the inconsistency between reciting a method to determine the ratio of an analyte to the total volume of a sample and, in the last step, calculating a ratio of the analyte to other components. Applicants have amended Claim 33 to change the last step to “calculating a ratio of the third quantity divided by the sum of the first quantity, the second quantity and the third quantity,” as suggested by the Examiner. Accordingly, Applicants respectfully request the Examiner to withdraw the objection to Claim 33.

Claim 36

The Examiner objects to Claim 36 for being indefinite by using the term “hemocrit.” Applicants have amended Claim 36 to change the term “hemocrit” to “hematocrit” as suggested by the Examiner. Accordingly, Applicants respectfully request the Examiner to withdraw the objection to Claim 36.

Response to Rejection of Claims 1-49 Under 35 U.S.C. § 101

In the May 3, 2006 Office Action, the Examiner rejected Claims 1-49 under 35 U.S.C. § 101 as lacking patentable utility. The Examiner states that “[m]ethods that lack a tangible product, or conveyance of a result (i.e. gedankenexperiments) are inadmissible.” However, the Examiner does not provide any support for this statement in 35 U.S.C. § 101, the M.P.E.P., or the case law.

Applicants respectfully traverse this argument. Applicants submit that the Examiner has not established a *prima facie* case of ineligible subject matter pursuant to 35 U.S.C. § 101. “The examiner bears the initial burden ... of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). As outlined in the “Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility,” if the record as a whole suggests that it is more likely than not that the claimed invention would be considered a practical application of an abstract idea, natural phenomenon, or law of nature, the Examiner should not reject the claim. Only when the claimed invention is devoid of any limitation to a practical application should it be rejected under 35 U.S.C. § 101. *See*, M.P.E.P. § 2107, p. 2100-7 (Rev. 3, August 2005)(emphasis added). Upon the Examiner

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identifying and explaining in the record the basis for why a claim is for an abstract idea with no practical application, the burden shifts to Applicants to either amend the claim or make a showing of why the claim is eligible for patent protection. *See, e.g., In re Brana*, 52 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); *see generally* M.P.E.P. § 2107. Applicants submit that the Examiner's statement in the May 3, 2006 Office Action that "[m]ethods that lack a tangible product, or conveyance of a result (i.e. gedankenexperiments) are inadmissible" does not present a *prima facie* case of unpatentability by explaining why the pending claims of the present application are devoid of any limitations to a practical application.

As explained in the "Interim Guidelines," a claimed invention must accomplish a practical application by producing a "useful, concrete and tangible result." (Citing *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F.3d 1373-74, 47 U.S.P.Q.2d 1601-02 (Fed. Cir. 1998); *see, also, Ex parte Lundgren*, Appeal No. 2003-2088, B.P.A.I. 2005). Furthermore, claims directed to transformations of data of a physical quantity (*e.g.*, infrared absorption data from a sample, as in the pending claims) produce a useful, concrete, and tangible result. *See*, M.P.E.P. § 2107, page 2100-16. Applicants submit that each of the pending claims of the present application includes limitations to a practical application by producing a useful, concrete, and tangible result, thereby conforming to the requirements of 35 U.S.C. § 101.

Applicants submit that the claimed invention of the pending claims provides a useful result that is specific, substantial, and credible in accordance with M.P.E.P. § 2107. For example, as described by the present specification at paragraphs [0003]-[0006], determining an analyte concentration in a sample (*e.g.*, glucose levels in blood samples) is an important part of health maintenance for people who suffer from various conditions (*e.g.*, diabetes). Other portions of the present specification, including but not limited to paragraphs [0210]-[0212], describe that in infrared (IR) absorption measurements, the contribution due to the analyte of interest (*e.g.*, glucose) is often only a small percentage of the contribution from other substances within the sample, and that IR absorption measurements are complicated by the presence of these other components. Therefore, persons of ordinary skill in the art understand that the claimed invention of methods of "determining an analyte concentration in a sample" as recited by Claims 1-8 and 10-24, methods of "providing measurements of constituents in a sample using infrared (IR) spectroscopy" as recited by Claims 27 and 30-32, methods of "using infrared (IR)

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spectroscopy to determine a ratio of an analyte volume to the total volume of a sample” as recited by Claims 33-38, methods of “determining non-analyte contributions to absorption data from a sample” as recited by Claims 29-44, methods of “evaluating analyte concentration errors in absorption data from a sample” as recited by Claims 45-48, and a method of “determining an optical pathlength of a sample” as recited by Claim 49 all provide a useful result that is specific, substantial, and credible.

In addition, Applicants submit that the claimed invention of the pending claims produces concrete results that can be substantially repeated to substantially produce the same results again. Applicants also submit that the claimed invention of the pending claims provides tangible results by setting forth a practical application with real-world results. By determining the various contributions to absorption data from the various constituents of a sample to correct the absorption data for a non-analyte contribution, to provide corrected absorption data, to determine a ratio of an analyte volume to the total sample volume, to calculate new estimates of absorption, or to determine analyte concentration error, the claimed invention of the pending claims provide a practical application with tangible, real-world results. Therefore, Applicants submit that the pending claims of the present application satisfy the requirements of 35 U.S.C. § 101 by producing a useful, concrete, and tangible result.

Furthermore, to the extent that the Examiner is asserting that the pending method claims of the present application encompass statutory subject matter only if they result in a physical transformation or contain a physical limitation, Applicants submit that 35 U.S.C. § 101 does not include such a requirement. This requirement was explicitly addressed in *Application of Foster*, 438 F.2d 1011, 1014 (C.C.P.A. 1971), which held that claims should not be rejected for lack of appropriate subject matter simply because they include steps that transform one mental concept into another. Moreover, in *AT&T Corp. v. Excel Communications Inc.*, 172 F.3d 1352, 1358-59 (Fed. Cir. 1999), the court explicitly held that the assertion that a method claims is patentable only if it results in a physical transformation or contains a physical limitation is incorrect for method claims. Additionally, the fact that no physical alteration is required is also supported by the Board’s decision in *Ex parte Lundgren*, which involved claims directed to a method of compensating a manager, where the claims did not recite a required physical alteration. Therefore, Applicants submit that the pending claims do not need to include “an LCD display.

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screen or similar device,” as suggested by the Examiner in the May 3, 2006 Office Action, in order to be directed to patentable subject matter under 35 U.S.C. § 101.

For the foregoing reasons, Applicants submit that Claims 1-49 satisfy the requirements of 35 U.S.C. § 101, and Applicants respectfully request the Examiner to withdraw the rejection.

Response to Rejection of Claims 1 and 25 Under 35 U.S.C. § 102(e)

In the May 3, 2006 Office Action, the Examiner rejected Claims 1 and 25 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,862,534, issued to Sterling et al. (“the ‘534 patent”).

Applicants have submitted a declaration by Applicants’ representative, Bruce S. Itchkawitz, under 37 C.F.R. § 1.132 declaring that the correct inventorship for this application is Bernhard B. Sterling, James R. Braig, Daniel Goldberger, and Kenneth G. Witte and that a petition under 37 C.F.R. § 1.48(a) to correct the inventorship of this application is being prepared. A copy of the declaration is enclosed herewith. Because the correct inventorship of the present application is the same as that of the ‘534 patent, Applicants respectfully submit that any invention disclosed but not claimed in the ‘534 patent is not the invention “by another.” Accordingly, the ‘534 patent is not properly cited as a §102(e) prior art reference of the present application. Applicants respectfully request the Examiner to withdraw this rejection.

Response to Rejection of Claims 1, 9-12, and 17-18 Under 35 U.S.C. § 102(b)

In the May 3, 2006 Office Action, the Examiner rejected Claims 1, 9-12, and 17-18 under 35 U.S.C. § 102(b) as being anticipated by “Spectroscopic Quantitative Analysis of Blood Glucose By Fourier Transform Infrared Spectroscopy With an Attenuated Total Reflection Prism,” by Kajiwarara et al. (“Kajiwarara”).

As currently amended, Claim 1 recites (emphasis added):

1. A method of determining an analyte concentration in a sample, the sample comprising the analyte and a substance, the method comprising:
 - providing absorption data of the sample;
 - providing reference absorption data of the substance;
 - calculating a substance contribution of the absorption data, wherein calculating the substance contribution comprises **scaling the reference absorption data by multiplying the reference absorption data by a scaling factor**; and
 - subtracting the substance contribution from the absorption data of the sample, thereby providing corrected absorption data of the analyte substantially free of a contribution from the substance.

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Applicants submit that Kajiwara does not disclose all the limitations recited by amended Claim 1. For example, Applicants submit that Kajiwara does not disclose “calculating a substance contribution of the absorption data” which comprises “scaling the reference absorption data by multiplying the reference absorption data by a scaling factor,” as recited by amended Claim 1.

Kajiwara at page 182, second column, lines 20-21 discloses obtaining the absorbance of molecules dissolved in an aqueous solution by “calculating the difference between [the absorption coefficients of the aqueous solution and distilled water].” However, Kajiwara does not disclose scaling the absorbance spectrum of the reference sample (*i.e.*, distilled water) by multiplying the reference sample absorption data by a scaling factor prior to calculating the difference between the absorption coefficients of the aqueous solution and distilled water. Thus, while Kajiwara discloses subtracting the reference substance absorption data from the sample absorption data, Kajiwara does not disclose calculating a substance contribution by “scaling the reference absorption data,” as recited by amended Claim 1 (emphasis added). Therefore, Applicants submit that amended Claim 1 is not anticipated by Kajiwara, so amended Claim 1 is patentable over Kajiwara.

Applicants have cancelled Claim 9 without prejudice. Each of amended Claims 10-12, 17, and 18 depends directly or indirectly from amended Claim 1, and therefore, is patentable for at least the same reasons that amended Claim 1 is patentable over the applied art. Applicants respectfully request the Examiner to withdraw the rejection of amended Claim 1 and Claims 10-12, 17, and 18 and pass these claims to allowance.

Response to Rejection of Claims 1, 9, 13, 18-26, and 31-32 Under 35 U.S.C. § 102(b)

In the May 3, 2006 Office Action, the Examiner rejected Claims 1, 9, 13, 18-26, and 31-32 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,115,673, issued to Malin et al. (“Malin”).

Applicants submit that Malin does not disclose all the limitations recited by amended Claim 1. For example, Applicants submit that Malin does not disclose “calculating a substance contribution of the absorption data” which comprises “scaling the reference absorption data by multiplying the reference absorption data by a scaling factor,” as recited by amended Claim 1.

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Malin discloses generating a basis set that “includes all interfering components found in a sample” (Malin, Col. 4: Lines 66-67) and “subtract[ing] each interferant from the spectra produced at the frequency of interest...leaving substantially only the signal produced by the analyte of interest.” (Malin, Col. 7: Lines 59-63). Malin further discloses that in some embodiments, “it is necessary to consider such factors as scatter correction, refractive index correction, depth of penetration into the tissue, total optical path, and temperature” (Malin, Col. 8: Lines 11-14), however Malin does not disclose “scaling the reference absorption data by multiplying the reference absorption data by a scaling factor,” as recited by amended Claim 1 (emphasis added). Therefore, Applicants submit that amended Claim 1 is not anticipated by Malin, so amended Claim 1 is patentable over Malin.

Applicants have cancelled Claims 9, 25, and 26 without prejudice. Each of Claims 13 and 18-24 depend directly or indirectly from amended Claim 1, and therefore, are patentable for at least the same reasons that amended Claim 1 is patentable over the applied art. Applicants respectfully request the Examiner to withdraw the rejection of amended Claim 1 and Claims 13 and 18-24 and pass these claims to allowance.

Each of Claims 31 and 32 has been amended to depend from amended Claim 30, which has been amended to be in independent form. As described above, Applicants submit that amended Claim 30 is in condition for allowance. Accordingly, Applicants submit that Claims 31 and 32 are also in condition for allowance, and Applicants respectfully request the Examiner to withdraw the rejection of Claims 31 and 32 and pass these claims to allowance.

Response to Rejection of Claims 33-38 Under 35 U.S.C. § 102(b)

In the May 3, 2006 Office Action, the Examiner rejected Claims 33-38 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0038079, issued to Steuer et al. (“Steuer”).

Claim 33

As currently amended, Claim 33 recites:

33. A method of using infrared (IR) spectroscopy to determine a ratio of an analyte volume to the total volume of a sample comprising the analyte, a first substance, and a second substance, the method comprising:

providing absorption data from the sample for a first set of wavelengths in a wavelength region where a first-substance absorption dominates;

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calculating a first quantity equal to the product of a first-substance volume concentration and a path length of the sample;

providing absorption data from the sample for a second set of wavelengths in a wavelength region where the first-substance absorption and a second-substance absorption dominate;

calculating a second quantity equal to the product of a second-substance volume concentration and the path length of the sample;

providing absorption data from the sample for a third set of wavelengths in a wavelength region where the first-substance absorption, the second-substance absorption, and an analyte absorption dominate;

calculating a third quantity equal to the product of an analyte volume concentration and the path length of the sample; and

calculating a ratio of the third quantity divided by the sum of the first quantity, the second quantity and the third quantity.

Applicants submit that Steuer does not disclose all the limitations recited by amended Claim 33. Steuer discloses a method and apparatus for non-invasive measurement of a constituent of a sample in a pulsatile environment. (Steuer, Paragraphs [0048], [0063]). In particular, Steuer discloses a modified Beer-Lambert equation, as shown in equation (2), for overcoming the changes in concentration as the blood layer pulsates. (Steuer, Paragraphs [0059]-[0063]). Steuer further calculates the partial derivatives of the modified Beer-Lambert equation, as shown in equation (5), and uses the value of these equations at different wavelengths to calculate the extinction coefficient ratio. (Steuer, Paragraphs [0068]-[0071]). Thus, Steuer is relying on the pulsatile environment, wherein the path length of light through the sample changes, and using partial derivatives to determine an extinction coefficient ratio for a constituent in a multi-component sample in order to determine the concentration of the constituent in the total sample.

Conversely, amended Claim 33 of the present application recites a method for determining the ratio of an analyte volume to a total sample in a static environment in which the path length does not change during the measurement. The method recited by amended Claim 33 includes calculating the product of the path length and the volume concentrations of individual constituents and using these products to determine the ratio of the analyte volume to the total volume of the sample.

Thus, while Steuer discloses using partial derivatives of a modified Beer-Lambert equation to determine the concentration of a constituent in a sample wherein the path length through the sample changes, Steuer does not disclose "calculating a first quantity equal to the

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product of a first-substance volume concentration and a path length of the sample,” “calculating a second quantity equal to the product of a second-substance volume concentration and the path length of the sample,” “calculating a third quantity equal to the product of an analyte volume concentration and the path length of the sample,” and “calculating a ratio of the third quantity divided by the sum of the first quantity, the second quantity, and the third quantity,” as recited by amended Claim 33.

Therefore, Applicants submit that amended Claim 33 is not anticipated by Steuer, so amended Claim 33 is patentable over Steuer. Each of Claims 34-38 depends from amended Claim 33 and, therefore, are patentable for at least the same reasons that amended Claim 33 is patentable over the applied art. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of Claims 33-38 and pass these claims to allowance.

Response to Rejection of Claim 49 Under 35 U.S.C. § 102(b)

In the May 3, 2006 Office Action, the Examiner rejected Claim 49 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,805,623, issued to Jöbsis et al. (“Jöbsis”). Applicants respectfully traverse this rejection.

Claim 49

Claim 49 recites:

49. A method of determining an optical pathlength of a sample comprising water and a whole blood protein, the method comprising measuring an optical absorption of the sample at an isosbestic wavelength and calculating the optical pathlength of the sample from the optical absorption.

Applicants submit that Jöbsis does not disclose all the limitations recited by Claim 49. For example, Applicants submit that Jöbsis does not disclose “measuring an optical absorption of the sample at an isosbestic wavelength and calculating the optical pathlength of the sample from the optical absorption,” as recited by Claim 49.

Jöbsis discloses calculating the apparent path length in an environment of unknown path length by taking the absorption measurements of a reference component in known concentration in the same electromagnetic spectral region, calculating the differential absorbance in the environment of unknown path length and using the “tabulated or previously determined extinction coefficient values of the pure reference component at such wavelengths” to determine the apparent path length. (Jöbsis, Col. 4: Lines 31-40). In contrast, as described by the present

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application, by measuring the absorption of a sample at an isosbestic wavelength, as recited by Claim 49, the measured absorption is independent of the sample concentration and is an indication of the total sample volume. Thus, a tabulated or previously determined extinction coefficient value is not needed, since the absorption is independent of the concentration of the constituents of the sample. While Jöbsis discloses determining the path length of an unknown environment by measuring the differential absorbance of a reference component of known concentration, Jöbsis does not disclose “measuring an optical absorption of the sample at an isosbestic wavelength and calculating the optical pathlength of the sample from the optical absorption,” as recited by Claim 49 (emphasis added).

Therefore, Applicants submit that Claim 49 is not anticipated by Jöbsis, so that Claim 49 is patentably distinguished over Jöbsis. Applicants respectfully request that the Examiner withdraw the rejection of Claim 49 and pass Claim 49 to allowance.

Response to Rejection of Claims 2-9 Under 35 U.S.C. § 103(a)

In the May 3, 2006 Office Action, the Examiner rejected Claims 2-9 under 35 U.S.C. § 103(a) as being unpatentable over Kajiwara in view of Steuer. As discussed above, Applicants submit that amended Claim 1 is patentably distinguishable over Kajiwara. Applicants further submit that Steuer does not disclose or suggest the limitations of amended Claim 1 which are not disclosed or suggested by Kajiwara. Therefore, amended Claim 1 is patentably distinguished over the combination of Kajiwara in view of Steuer. Claims 2-8 depend directly or indirectly from amended Claim 1. Claim 9 has been cancelled without prejudice. Therefore, Applicants submit that Claims 2-8 are patentable over the combination of Kajiwara in view of Steuer. Applicants respectfully request that the Examiner withdraw the rejection of Claims 2-8 and pass these claims to allowance.

Response to Rejection of Claims 28 and 29 Under 35 U.S.C. § 103(a)

In the May 3, 2006 Office Action, the Examiner rejected Claim 28 under 35 U.S.C. § 103(a) as being unpatentable over Malin in view of U.S. Patent No. 5,876,121 issued to Burns and rejected Claim 29 under 35 U.S.C. § 103(a) as being unpatentable over Malin in view of U.S. Patent No. 6,441,388, issued to Thomas.

Applicants have cancelled Claims 28 and 29 without prejudice.

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CONCLUSION

In view of the foregoing remarks, Applicants submit that Claims 1-8, 10-24, 27, and 30-49 are in condition for allowance and Applicants respectfully request such action. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 4/2/06

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